REMARKS

Applicant affirms his previous provisional election to combine claims 6-7 of invention II with claims 1-2 of invention I for examination. Reconsideration and reexamination of this application, as amended, is respectfully requested. Claims 1-2 and 6-10 are pending in this application. Claim 6 has been amended. Claims 8-10 have been added.

A. Formal Specification Rejections

The Examiner indicated that two consecutive examples were numbered Example 3, while Example 5 was missing. Applicant has amended the specification to correct this error.

The Examiner indicated that the title of the invention was not descriptive. Applicant has substituted the previous title with the following new title: **METHOD OF IDENTIFYING MISSING DOMAINS IN RECEPTORS**. Applicant submits this new title is clearly indicative of the invention.

B. Claim Rejections Under 35 U.S.C. § 112

The Examiner rejected claims 1-2 under 35 U.S.C. § 112, first paragraph, as being non-enabled. The Examiner suggests that while the claim is clearly enabling for a method of identification of missing domains of the calcitonin, glucagon, and somatostatin receptors, it is not enabling for the identification of the missing domains of all other receptors. Applicant respectfully traverses this rejection.

The specification of a patent application is presumptively enabling. *In re Marzocchi*, 157 USPQ 502 (CCPA 1968). Here, the entire specification provides a sound scientific basis and description for the claimed subject matter. Neither the claims nor the specification are construction blueprints. They are addressed to one of skill in the art. To support a rejection for non-enablement under 35 U.S.C. § 112, first paragraph, in view of the well-structured specification and its presumptive enablement, the Office must cite references which show, *inter alia*, that the specific model utilized here does not translate into other

models. Conclusions not supported by references do not create a *prima facie* case of non-enablement which forces the Applicant to go forward with rebuttal evidence.

The Examiner asserts that it would require undue experimentation to identify the physiological activity of the missing domain of each specific receptor, because it is not feasible for one of skill in the art to employ the same procedures for more than one receptor at a time. Applicant asserts this is not the standard for enablement.

In *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), the court discussed the standard for enablement:

> A considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.

In re Angstadt, 190 USPQ 214, 218 (CCPA 1976) further illustrates why a disclosure of limited examples in the specification can be enabling for a claim of much broader scope.

> Appellants have apparently not disclosed every catalyst which will work; they have apparently not disclosed every catalyst which will not work. The question, then, is whether in an unpredictable art, Section 112 requires disclosure of a test with every species covered by a claim. To require such a complete disclosure would apparently necessitate a patent application or applications with "thousands" of examples or the disclosure of "thousands" of catalysts along with information as to whether each exhibit's catalytic behavior resulted in the production of hydroperoxides. More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims will have to be limited to those embodiments which are expressly disclosed.

Applicant submits that the specification here provides a reasonable amount of guidance as to the direction in which the experimentation should proceed. The examples in the specification provide adequate guidance as to the identification of the missing domains, the synthesis of the peptides, and the testing of the peptides' functionality as it relates to the function of the receptor. While a considerable amount of experimentation may be necessary

to identify the missing domains of "all other receptors," this experimentation is merely routine.

Applicant submits that like the patentee in *In re Angstadt*, a disclosure specifying all examples of the identification of missing domains would not be feasible.

The Examiner rejected claim 2 based on its dependence of claim 1. Applicant respectfully traverses this rejection. Claim 2 is directed to a much narrower subset of receptors than claimed in claim 1. Thus, a separate analysis of enablement should have been conducted. Indeed, the subset of receptors claimed in claim 2 is drastically smaller than that of claim 1 because only 7-transmembrane type receptors are claimed. As disclosed above, the specification provides reasonable guidance with respect to how the experimentation should proceed in identifying other 7-transmembrane type receptors than those disclosed in the specification. Withdrawal of the rejection of claims 1-2 under 35 U.S.C. § 112, first paragraph, as being non-enabled is requested.

C. ***Rejections Under 35 U.S.C. § 102(b)***

The Examiner rejected claims 6-7 under 35 U.S.C. § 102(b) as being anticipated by WO9310149. WO9310149 teaches a human calcitonin receptor (CTR) which has 16 amino acid subsequence that is 100% identical to SEQ. ID. NO: 1. This reference teaches this sequence in the context of the human calcitonin receptor, not as isolated peptide sequence.

Claim 6 was amended so that it no longer claims SEQ. ID. NO: 1. Thus, it is submitted that claim 6 is now allowable.

Claim 8 was added which is directed to a peptide with an amino acid sequence of SEQ. ID. NO: 1. Use of the "consisting of" transitional phase in claim 1 limits the breadth of the claim to the 16 amino acid peptide described in SEQ. ID. NO: 1. Because WO9310149 is a polypeptide of much greater length than 16 amino acids, it is submitted that this reference does not anticipate claim 8 or its dependent claims 9-10. Withdrawal of this rejection is respectfully submitted.

D. ***Summary***

Claims 1-2, claim 6 as amended, and new claims 8-10 contain substantive requirements for patentability. Applicant has made a genuine effort to respond to the Examiner's objections and rejections in advancing the prosecution of this case. Applicant believes all formal and substantive requirements for patentability have been met and that this case is in condition for allowance, which action is respectfully requested.

A check in the amount of $200.00 (small entity status) is enclosed to cover the two month Petition For Extension of Time fee. Please charge any additional fees or credit any overpayments as a result of the filing of this paper to our Deposit Account No. 02-3978 — a duplicate of this page is enclosed for that purpose.

The Examiner is requested to telephone the undersigned to discuss prompt resolution of any remaining issues necessary to place this case in condition for allowance.

Respectfully submitted,

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By _____

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Attachment

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In The Substitute Specification

On page 7, please replace the second full paragraph with the paragraph below:

[Example [3] 4] Presence on osteoblasts of the receptors of the peptides of the present invention:

On page 9, please replace the second full paragraph with the paragraph below:

[Example [4] 5] Identification of the missing domain in glucagon receptors:

In The Claims

6. (Amended) An isolated peptide [which] wherein said isolated peptide [is] comprises an amino acid sequence selected from the group consisting of [SEQ. ID. NO: 1,] SEQ. ID. NO: 2[,] and SEQ. ID. NO: 3.